prescription drug sales after application of the percentage adjustment table in section 9008(b)(2) (relating to annual sales less than $400,000,001). See §51.5(a)(3).

(m) *Sales year*. The term *sales year* means the second calendar year preceding the fee year. Thus, for example, for the fee year of 2014, the sales year is 2012.

[T.D. 9684, 79 FR 43639, July 28, 2014]

§51.2T Explanation of terms (temporary).

(a) Through (e)(2) [Reserved]. For further guidance see §51.2(a) through (e)(2).

(3) *Controlled Group*. The term *controlled group* means a group of two or more persons, including at least one person that is a covered entity, that is treated as a single employer under section 52(a), 52(b), 414(m), or 414(o).

(e)(4) through (m) [Reserved]. For further guidance see §51.2(e)(4) through (m).

[T.D. 9684, 79 FR 43639, July 28, 2014]

§51.3 Information requested from covered entities.

(a) *In general*. Annually, each covered entity may submit a completed Form 8947, ''Report of Branded Prescription Drug Information,'' in accordance with the instructions for the form. Generally, the form solicits information from covered entities on NDCs, orphan drugs, designated entities, rebates, and other information specified by the form or its instructions.

(b) *Due date*. Form 8947 must be filed by the date prescribed in guidance in the Internal Revenue Bulletin.

[T.D. 9684, 79 FR 43641, July 28, 2014]

§51.4 Information provided by the agencies.

(a) *In general*. For each sales year, the IRS will compile a list of branded prescription drugs by NDC using the data submitted on Forms 8947 and in error reports submitted as part of the dispute resolution process (described in §51.7) and, after applying appropriate due diligence, will provide this list to the Agencies. The Agencies will provide data to the IRS on branded prescription drug sales that occurred during the sales year by Program and NDC. The Agencies will provide data for use in preparing the preliminary fee calculation (described in §§51.5 and 51.6) and may revise or supplement that data following review of error reports submitted as part of the dispute resolution process. The calculation methodology for calculating the sales amounts for each Program, including any reasonable estimation techniques and assumptions that the Agencies expect to use, is described in this section.

(b) *Medicare Part D*—(1) *In general*. CMS will determine branded prescription drug sales under Medicare Part D by aggregating the ingredient cost reported in the ''Ingredient Cost Paid'' field on the Prescription Drug Event (PDE) records at the NDC level, reduced by discounts, rebates, and other price concessions provided by the covered entity, for each sales year. CMS will only include PDE data that Part D sponsors have submitted by the PDE submission deadline (within 6 months after the end of the sales year) and that CMS has approved for inclusion in the Part D payment reconciliation.

(2) *Discounts, rebates, and other price concessions*—(i) *In general*. For purposes of paragraph (b)(1) of this section, the term *discounts, rebates, and other price concessions* means:

(A) Any direct and indirect remuneration (DIR) (within the meaning of paragraph (b)(2)(ii) of this section), which includes any DIR reported on the PDE records at the point of sale and any DIR reported on a Detailed DIR Report (within the meaning of a paragraph (b)(2)(iii) of this section); and

(B) Any coverage gap discount amount (within the meaning of paragraph (b)(2)(iv) of this section).

(ii) *Direct and indirect remuneration*. For purposes of paragraph (b)(2)(i)(A) of this section, the term *direct and indirect remuneration* (DIR) has the same meaning as found in the definition of *actually paid* in 42 CFR 423.308.

(iii) *Detailed DIR Report*. For purposes of paragraph (b)(2)(i)(A) of this section, the term *Detailed DIR Report* means the report containing any DIR (within the meaning of paragraph (b)(2)(ii) of this section) that is collected yearly from Part D sponsors at the NDC level.

(iv) *Coverage gap discount amount.* For purposes of paragraph (b)(2)(i)(B) of this section, the term *coverage gap discount amount* means a 50-percent manufactured-paid discount on certain drugs under the Coverage Gap Discount Program described in section 1860D–14A of the Social Security Act.

(c) *Medicare Part B*—(1) *In general.* CMS will determine branded prescription drug sales under Medicare Part B using the following two data sources:

(i) CMS will use data reported by manufacturers pursuant to section 1847A(c) of the Social Security Act to calculate the annual weighted average sales price (ASP) for each Healthcare Common Procedure Coding System (HCPCS) code for the sales year.

(ii) CMS will use the Medicare Part B National Summary Data File located at *http://www.cms.gov/NonIdentifiableDataFiles/03__PartBNationalSummaryDataFile.asp* to obtain the number of allowed billing units per HCPCS code for claims incurred during the sales year.

(2) *Calculation*—(i) *In general.* Using the data described in paragraph (c)(1) of this section, CMS will determine branded prescription drugs sales under Medicare Part B as described in paragraphs (c)(3), (4), and (5) of this section. CMS reports sales amounts per HCPCS billing code, not per NDC. Therefore, a covered entity's total Part B sales amounts for all NDCs in a given HCPCS billing code appears under only one NDC in each HCPCS billing code and the covered entity's remaining NDCs in the HCPCS billing code are listed with a sales amount of zero.

(ii) *Example of a Part B sales report:*

HCPCS	NDC	Part B amount
J9876	12345–6789–01	$789,000
	12345–6789–02	0
	12345–6789–03	0
	12345–6800–80	0
	12345–6800–90	0

(3) *HCPCS code; single entity.* For each HCPCS code consisting solely and exclusively of branded prescription drugs (as identified by their respective NDCs) manufactured by a single entity, CMS will multiply the annual weighted ASP by the total number of allowed billing units paid during the sales year to determine the total sales for all NDCs associated with the HCPCS code attributed to Medicare Part B.

(4) *HCPCS code; multiple manufacturers and/or multiple drugs*—(i) *Step one.* For each HCPCS code consisting of a mixture of branded prescription drugs made by different manufacturers and/or a mixture of branded prescription and generic drugs, CMS will determine—

(A) The annual weighted ASP for the HCPCS code;

(B) The total number of allowed billing units paid by Medicare Part B for each HCPCS code during the sales year;

(C) The names of the entities engaged in manufacturing each NDC assigned to the HCPCS code; and

(D) Those entities (if any) identified in paragraph (c)(4)(i)(C) of this section that are manufacturing branded prescription drugs assigned to the HCPCS code.

(ii) *Step two.* Using the information from paragraph (c)(4)(i) of this section, CMS will then do the following:

(A) Calculate the proportion of sales, expressed as a percentage, attributed to each NDC assigned to the HCPCS code by determining the percentage of total sales reported to CMS by each manufacturer of NDC(s) that are assigned to the HCPCS code. For example, if HCPCS code JXXXX contains three drugs with a total of $310,000 sales reported by manufacturers to CMS for the sales year, and $100,000 was reported for Drug A, $200,000 was reported for Drug B, and $10,000 was reported for Drug C, the proportion of sales attributed to each NDC will be 32.26 percent for Drug A, 64.52 percent for Drug B, and 3.22 percent for Drug C; and

(B) For each NDC, multiply the product of the annual weighted ASP and the total allowed billing units paid by Medicare Part B for the HCPCS code by the proportion of sales calculated in paragraph (c)(4)(ii)(A) of this section to determine the sales reportable to the IRS (that is, percentage × (annual weighted ASP × allowed units) = total sales reported to IRS for the NDC). The sales for each manufacturer's NDCs assigned to a HCPCS code are summed

and the total sales for each manufacturer's NDCs in a HCPCS code will be reported to the IRS.

(5) *HCPCS code; unable to establish a reliable proportion of sales.* If CMS is unable to establish a reliable proportion of sales attributable to each NDC assigned to the HCPCS code using the method described in paragraph (c)(4)(ii)(A) of this section, CMS will use Medicare Part D utilization percentages in lieu of the proportion of sales determined under paragraph (c)(4)(ii)(A) of this section to perform the calculation described in paragraph (c)(4)(ii)(B) of this section.

(d) *Medicaid.* (1) CMS will determine the branded prescription drug sales for Medicaid as the per-unit Average Manufacturer Price (AMP) less the Unit Rebate Amounts (URA) that CMS calculates based on manufacturer-reported pricing data multiplied by the number of units reported billed by states to manufacturers. This data will be based on the data reported to CMS for the sales year by covered entities and the states for drugs paid for by the states in the Medicaid Drug Rebate Program for the sales year. The data will include all branded prescription drug units for which the states bill rebates to covered entities under the Medicaid Drug Rebate Program. This program includes, but is not limited to, units paid for under various health care plans such as fee for service, managed care organizations, and drugs administered in a non-retail setting such as drugs administered in a physician's office, clinic, hospital or other setting. The Medicaid Drug Rebate Program's calculated branded prescription drug fee does not include state-only pharmaceutical program sales or rebates.

(2) For any covered entity identified in the first five (or six) digits of an NDC during any of the four quarters of a sales year, CMS will use the following methodology to derive the sales figures that account for third-party payers, such as Medicare Part B:

(i) Report total dollars per NDC for AMP minus URA multiplied by the units reported by a state or states.

(ii) Determine the percentage of the total amount reimbursed that is the Medicaid amount of that reimbursement. For example, if the total amount reimbursed is $100,000, and the Medicaid amount reimbursed is $20,000, then the percentage is 20 percent.

(iii) Multiply the percentage of the Medicaid amount of that reimbursement (in the example in paragraph (d)(2)(ii) of this section, 20 percent) by the dollar figure derived from paragraph (d)(2)(i) of this section (AMP minus URA multiplied by units) to get the new adjusted sales dollar totals.

(e) *Department of Veterans Affairs.* VA will determine branded prescription drug sales to VA by providing, by NDC, the total amount paid (net of refunds and rebates, when they are associated with a specific NDC) for each branded prescription drug procured by VA for its beneficiaries during the sales year. For this purpose, a drug is procured on the invoice (billing) date. The basis of this information will be national procurement data reported during the sales year by VA's Pharmaceutical Prime Vendor to the VA Pharmacy Benefits Management Service and National Acquisition Center. VA sales data includes the Industrial Funding Fee and the Cost Recovery Fee because these amounts are part of the price VA pays to its Pharmaceutical Prime Vendor to procure a drug.

(f) *Department of Defense.* DOD will determine branded prescription drug sales to DOD (for DOD programs other than the TRICARE retail pharmacy program) by providing, by Labeler Code, the manufacturer's name, the NDC, brand name, and the amount paid (net of rebates and or refunds) for each branded prescription drug procured by DOD (for DOD programs other than the TRICARE retail pharmacy program) during the sales year. For DOD programs other than the TRICARE retail pharmacy program, a drug is procured based upon the date it was ordered. DOD includes the Industrial Funding Fee and the Cost Recovery Fee in its drug sales data because these amounts are part of the price DOD pays to procure a drug.

(g) *TRICARE.* DOD will determine branded prescription drug sales to DOD for the TRICARE retail pharmacy program by providing, by Labeler Code, the manufacturer's name, the NDC, brand name, and the amount paid (net of rebates or refunds) for each branded

prescription drug procured by DOD through the TRICARE retail pharmacy program during the sales year. For the TRICARE retail pharmacy program, a drug is procured based upon the date it was dispensed. The amount paid is based on the submitted ingredient cost paid, aggregated by NDC, for eligible TRICARE retail pharmacy claims submitted during the program year, minus any refunds or rebates for the corresponding claims.

[T.D. 9684, 79 FR 43641, July 28, 2014; 79 FR 57784, Sept. 26, 2014]

§ 51.5 Fee calculation.

(a) *Fee components*—(1) *In general.* For every fee year, the IRS will calculate a covered entity's total fee as described in this section. The IRS will determine a covered entity's total fee by applying, if applicable, the adjustment amount described in paragraph (e) of this section to the entity's allocated fee described in paragraph (d) of this section.

(2) *Calculation of branded prescription drug sales.* Each covered entity's allocated fee for any fee year is equal to an amount that bears the same ratio to the applicable amount as the covered entity's branded prescription drug sales taken into account during the sales year bears to the aggregate branded prescription drug sales of all covered entities taken into account during the sales year.

(3) *Applicable amount.* The applicable amounts for fee years are—

Fee year	Applicable amount
2011	$2,500,000,000
2012	2,800,000,000
2013	2,800,000,000
2014	3,000,000,000
2015	3,000,000,000
2016	3,000,000,000
2017	4,000,000,000
2018	4,100,000,000
2019 and thereafter	2,800,000,000

(4) *Sales taken into account.* A covered entity's branded prescription drug sales taken into account during any calendar year are as follows:

Covered entity's branded prescription drug sales during the calendar year that are:	Percentage of branded prescription drug sales taken into account is:
Not more than $5,000,000	0
More than $5,000,000 but not more than $125,000,000	10
More than $125,000,000 but not more than $225,000,000	40
More than $225,000,000 but not more than $400,000,000	75
More than $400,000,000	100

(b) *Determination of branded prescription drug sales.* The IRS will compile each covered entity's branded prescription drug sales for each Program by NDC. Each NDC will be attributed to the covered entity identified in the Labeler Code as of the end of the day on December 31st of the sales year. For a covered entity that is a controlled group, this includes all NDCs in which a member of the covered entity is identified. For this purpose, the IRS may revise the list of NDCs as a result of information received in the dispute resolution process, and the data the IRS uses to produce the final fee calculation will include any revisions provided by the Agencies at the completion of the dispute resolution process. Each covered entity's branded prescription drug sales will be reduced by its Medicaid state supplemental rebate amounts in the following manner. If CMS has Medicaid state supplemental rebate information for a sales year, CMS will report to the IRS branded prescription drug sales for Medicaid net of Medicaid state supplemental rebates. If CMS does not have complete Medicaid state supplemental rebate information for a sales year, the IRS will reduce the branded prescription drug sales that CMS reported for Medicaid by Medicaid state supplemental rebates reported by the covered entities on Form 8947.

(c) *Determination of sales taken into account.* (1) For each sales year and for each covered entity, the IRS will calculate sales taken into account. The resulting number is the numerator of the ratio described in paragraph (d)(1) of this section.

(2) For each sales year, the IRS will calculate the aggregate branded prescription drug sales taken into account for all covered entities. The resulting